

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/17/2010 has been entered.

### ***Acknowledgments***

2. In the reply, the applicant amended claims 11, 14, 16, 23, 24, and 25.
3. Thus, claims 11, 14-27 are pending for examination.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 14-16 and 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al (US 7,004,961; see also provisional application 60/438904).  
Wong teaches a method of treating a subdural hematoma comprising the steps of:

Inserting a dual-lumen catheter (174, Fig 6) into a subdural space (Fig 8); draining said subdural space (via catheter F and drainage port 184A); and irrigating said subdural space (via catheter E and irrigation port 183A). See Col 9 lines 50+: "The device (174) may alternatively include another irrigation catheter E and another aspiration catheter F disposed within the tube 176 and communicate with connectors 183, 184 respectively. The distal end of irrigation catheter E exits through a side port 183A in device 174 to reside in the subarachnoid/subdural space(s) 70. Similarly, the distal end of aspiration catheter F also exits through a side port 184A in device 174 which would reside in the subarachnoid/subdural space(s) 70."

As to claim 18, see pressure valve 152 and 216, Fig 9. As to claim 19, see irrigation container 222, Fig 9. As to claim 20, see luer lock 218. As to claim 21, see drainage container 224. See response to arguments below.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 14-16, 18-21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (7004961) in view of Thomas (6358536). Wong teaches the invention substantially as claimed as described above. In the event that it is argued that Wong et al does not teach accessing a subdural space without penetrating the brain, this teaching of Thomas may be applied as described below.

6. Thomas teaches that it is known to insert a catheter into a subdural space without penetrating the brain (Fig 8a-d; Example 6) for the purpose of providing access to the subdural space of the skull without penetrating the brain (see Example 6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the introducer and method as taught by Wong et al with the introducer and method as taught by Thomas for the purpose of providing catheter access to the subdural space of the skull without penetrating the brain (see Example 6).

3. Claims 17, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong and Thomas as applied to claims above.

Claim 17: Wong does not teach the size of his drainage perforations. Since the applicant has not stated that the size of the drainage holes solves a stated problem or serves a particular purpose, and because both the holes of Wong and the applicant's holes are designed to drain fluid from the subdural space, it would have been a matter of obvious design choice to make the holes of Wong .5 to 2 mm in diameter.

Claims 22, 25: Wong does not specifically teach drilling a hole in the skull. Wong shows his catheter inserted into the skull 72 through "surgical opening" 62. Fig 4. One of ordinary skill in the art would recognize that drilling is a common way to open a hole in a bone, especially the skull, and would have expected drilling to produce a surgical opening in the skull. Further, Thomas explicitly teaches drilling a hole (see Surgical Procedure).

5. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong and Thomas as applied to claims above, and further in view of DARDIK et al (Journal of Vascular Surgery).

Wong and Thomas teaches the limitations of the dual lumen catheter as above, but is silent on the duration of irrigation and drainage of the subdural hematoma.

Dardik et al teach that drains are removed from patients after three days (Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the dual lumen catheter for three days, as taught by Dardik et al, as a well known medical procedure.

6. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong and Thomas as applied to claims above, and further in view of Kizelshteyn et al (5215105).

Wong and Thomas teach the limitations as discussed above, except for the touhy needle having a curved tip.

Kizelshteyn et al teaches a touhy needle with a curved tip (28d) for the purpose of enabling the distal outlet of the introducer to be more closely oriented to the longitudinal axis of the body cavity or to provide initial direction to the catheter toward a specific area of the body cavity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the touhy introducer as taught by Wong et al and Thomas with curved tip as taught by Kizelshteyn et al for the purpose of enabling the distal outlet of the introducer to be more closely oriented to the longitudinal axis of

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the body cavity or to provide initial direction to the catheter toward a specific area of the body cavity.

***Response to Arguments***

7. Applicant's arguments filed 8/18/2009 have been fully considered but they are not persuasive.

8. Applicant argues that Wong et al teaches a step of penetrating the brain. This is not persuasive. Wong et al discloses the step of introducing the catheters in the alternative.

9. The stylet may include a fiber-optic camera and/or ultrasound navigational instrumentation If this fiber-optic camera is inserted into the conduit, the rigid lens at the distal end of the conduit allows the conduit to penetrate through the surgical opening in the skull as well as the brain parenchyma to any region of the brain including the subarachnoid and/or subdural space and/or the lateral ventricle, or any other opening in the central nervous system (CNS). (col 3, lns 25-33) (emphasis added).

10. As illustrated in FIG. 2, the stylet 14 is inserted into the conduit 12 and a distal end 24 of the conduit 12 penetrates brain tissue 60 through a surgical opening 62. As shown in FIG. 2, the distal end 24 resides within a lateral ventricle 68 while the side ports 16, 18, 20 on the conduit may be open to the

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subarachnoid/subdural space(s) 70. The conduit 12 may have variations in placement in other brain spaces, or cavities, such as, for example the subarachnoid space 70, as hereinafter described. The conduit 12 may have variations in design such that no side holes are provided for openings to the subarachnoid/subdural space(s) 70. The conduit 12 may have its distal end 24 in the lateral ventricle or its distal end 24 in the subarachnoid/subdural space(s) 70. (col 8, lns 24-36) (emphasis added).

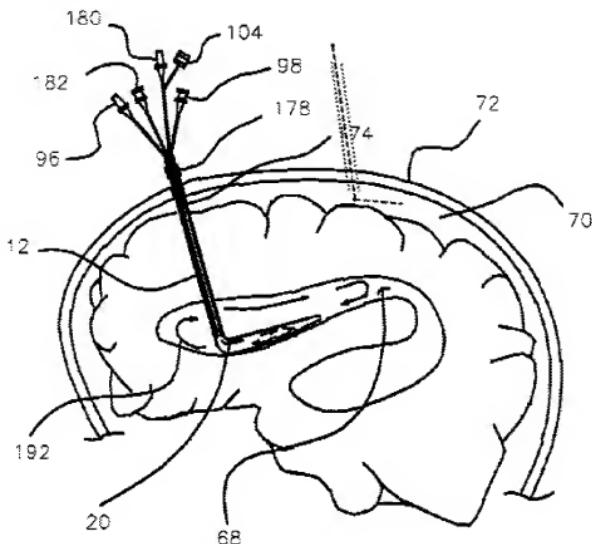


Fig. 8

Here, as shown in the annotated Fig 8 above, Wong et al discloses that the introducer is capable of penetrating the brain, but that it is not required to do so in

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certain instances where it is desired to access a certain area, such as the subdural area. As annotate, Fig 8 via dotted lines shows how the introducer would provide access to the subdural space (70) for the catheter without penetrating the brain.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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